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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/678,023 | 10/04/2000 | HIDEKI KAWASAKI | 5.1158 DIV I | 1950 |
| 5514 | 7590 | 05/19/2004 | EXAMINER | |
| FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | WALICKA, MALGORZATA A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |
| DATE MAILED: 05/19/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/678,023 | KAWASAKI ET AL. |
| | Examiner Malgorzata A. Walicka | Art Unit 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3-14 is/are pending in the application.
 - 4a) Of the above claim(s) 3,10 and 14 is/are withdrawn from consideration.
- 5) Claim(s) 7 is/are allowed.
- 6) Claim(s) 4-6, 8 and 11-13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10/04/00 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 08/894,344.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/04/00, 02/04/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

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The Response to Restriction Requirement filed on April 21, 2004 is acknowledged. Claims 3-14 are pending; claims 3, 10 and 14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 4-9 and 11-13 are elected and are the subject of this Office Action.

DETAILED ACTION

1. Election/Restriction

Applicant's election, with traverse, of Group II, claims 4-9 and 11-13 is acknowledged. The traversal is on the ground(s) that "claims to the nonelected process should be rejoined when a product claim is found allowable and the withdrawn process contains all the limitations of an allowed product claim."

Applicants' arguments are found persuasive. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Priority

Acknowledgment is made of Applicants' claim for priority based on PCT/JP96/03862 application, filed December 27, 1996 and Japanese application 34700/95 filed December 28, 1995. The priority of SEQ ID NO: 1 and 2 is not granted.

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Neither the PCT application nor the Japanese application disclose SEQ ID NO: 1 and 2 of the instant application.

3. Objections

3.1. Specification

It is noted that the first sentence of the specification claims, according to the preliminary amendment, the benefit of the filing date of an earlier filed US application No. 08/94,344. This application is now US Patent No. 6,172,169. The current status of the parent nonprovisional application should be included.

On page 3 line 14, and many places in the text, please replace "amino acid sequence represented by SEQ ID NO: 1" by "amino acid sequence of SEQ ID NO: 2" or "amino acid sequence set forth by SEQ ID NO: 2".

On page 3 line 19, and many places in the specification, please replace "DNAs" with "nucleotides".

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

3.2. Abstract

The abstract is objected to because the amino acid sequence is in error quoted as SEQ ID NO: 1. SEQ ID NO: 1 is a nucleotide sequence. Also, the word DNAs is used in the meaning of nucleotides. Please correct.

4. Rejections

4.1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 4 recites the limitation "the gene according to Claim 1 or 2". There is insufficient antecedent basis for this limitation in the claim, because claims 1 and 2 are canceled. Dependent claims 5, 6, 8, 9, 12, and 13 are included in the rejection because they do not correct the language of the rejected base claim.

Currently cancelled, original claims 1 and 2 will be used by the examiner as a reference to understand claims 4-6, 8-9 and 12-13.

4.2. 35 USC, section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.2.1. Lack of written description

Claims 4, 5, 6, 8, 9, and 11-13 are rejected because they are directed to yeast, or process of its use, belonging to any species of *Saccharomyces* wherein said yeast is low-temperature sensitive because the chromosomal gene complementing sensitivity to low temperature (CSF1, i.e., gene of SEQ ID NO: 1, or its modifications comprising deletions, additions or substitutions of one or more nucleotides) is inactivated.

Claims are generic, because they are directed to cells of genus *Saccharomyces* comprising natural or man-made functional variant of SEQ ID NO: 1, wherein said variant is inactivated. Functional variants of SEQ ID NO: 1 are lacking sufficient structural written description. Applicants do not disclose the function/structure relationship for SEQ ID NO: 1, and do not provide any guidance how to modify SEQ ID NO: 1 by additions, substitutions and deletions of at least one nucleotide so that the variant retained the required function. Thus, predictability of the structure of the claimed genus is not obvious. One skilled in the art realizes that even one change in the nucleotide sequences leading to the change of one amino acid may render the encoded protein inactive or change its activity completely. The specification discloses a single representative of the claimed genus, which is the polynucleotide of SEQ ID NO: 1. This is, however not sufficient for structural identification of the whole genus of functional variants of SEQ ID NO: 1 as well as all native CSF genes of all the species belonging to the genus *Saccharomyces*. The specification is silent as to what is the structure of homologous genes in, for example, *S. candida* or *pichia*, and to which degree such

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genes are homologous to SEQ ID NO: 1. Do they all comprise in positions 4388-7885 the fragments that are functionally equivalent to nucleotides 4388-7885 of SEQ ID NO: 1, so that disruption of these fragments prevents the complementation? The knowledge of function/structure of gene is crucial for its inactivating.

In conclusion, the claims are rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4.2.2. Scope of enablement

Claim 4, 5, 6, 8, 9, and 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inactivating CSF1 gene of SEQ ID NO: 1 isolated from *Saccharomyces cerevisiae*, does not reasonably provide enablement for any functional variant of SEQ ID NO: 1 and for CSF genes of all species of genus *Saccharomyces*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the

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nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses a microorganism of genus *Saccharomyces* comprising any natural or man-made functional variant of SEQ: 1 whose structure is obtained by additions, substitutions and deletions of at least one nucleotides of SEQ ID NO: 1, wherein said variant is inactivated by a person skilled in the art.

While gene manipulations and skills of those in the art are well developed, the breath of the claims that includes any an extremely large number of SEQ ID: 1 variants (SEQ ID NO: 1 consists of 8874 nt!) that are to be created by additions, substitutions and deletions of at least one nucleotides, forces one skilled in the art to manipulation and screening beyond the routine experimentation. When a large amount of manipulation and screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the functionality of CSF gene. The provision of SEQ ID NO: 1 fails to provide such guidance of polynucleotides with major structural variations therefrom which remain encompassed within the scope CSF genes of the rejected claims. The knowledge of the structure of the CSF gene is crucial for its inactivation. Therefore, lack of the guidance as to the direction in which modification of

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SEQ ID NO: 1 should go to obtain the functional equivalent of SEQ ID NO: 1 makes the probability of success in inactivating of such gene low.

Without a further guidance on the part of Applicants with regards to the structure of the claimed inventions experimentation left to those in the art is improperly extensive and undue.

5. Conclusion

Claim 7 is allowed. The following is examiner's reason for allowable subject matter.

Applicants disclose *Saccharomyces cerevisiae* YHK1234 (FERM BP-5327), the line having inactivated a gene for complementing sensitivity to fermentation in low temperature. The modified yeast is very useful in backing and production of ethanol. No prior art anticipates or fairly suggest this invention.

The yeast line was deposited under the term of Budapest Treaty, with the National Institute of Bioscience and Human Technology, Agency of Industrial Science and Technology, Ibaraki, Japan on Dec. 28, 1995; see the Notice Re Deposit of Microorganisms, filed on Sep. 22, 1999, in the parental case 08/994,344.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944 and the right fax number is (571) 273-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. EST.

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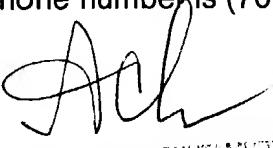
If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


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